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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/926,817 | 12/21/2001 | Yukihiro Fujieda | 217411US0 XPCT | 4758 |
| 22850 | 7590 | 04/01/2004 | | |
| OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | EXAMINER BRUENJES, CHRISTOPHER P | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1772 | |

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|---------------------------------------|--|
| Office Action Summary | Application No. 09/926,817 | Applicant(s) FUJIEDA ET AL. | |
| | Examiner Christopher P Bruenjes | Art Unit 1772 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-26, 28-30, 32-51, 53-55 and 57-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-26, 28-30, 32-51, 53-55 and 57-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 18, 2003 has been entered.

WITHDRAWN REJECTIONS

2. The 35 U.S.C. 112 rejections of claims 18-62 of record in the Office Action mailed June 18, 2003, Pages 3-5 Paragraphs 8-9, have been withdrawn due to Applicant's amendments in the Paper filed November 18, 2003.

3. The 35 U.S.C. 102 rejections of claims 18-20, 22-36, 41-43, and 45-58 as anticipated by Kodama et al of record in the Office Action mailed June 18, 2003, Pages 5-6 Paragraph 10, have been withdrawn due to Applicant's amendments and arguments in the Paper filed November 18, 2003.

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4. The 35 U.S.C. 103 rejections of claims 21, 37-40, 44, and 59-62 over Kodama et al of record in the Office Action mailed June 18, 2003, Pages 7-9 Paragraph 11-12, have been withdrawn due to Applicant's amendments and arguments in the Paper filed November 18, 2003.

5. The 35 U.S.C. 103 rejections of claims 18-31, 35, 37-45, and 49-62 over Heilmann et al in view of Strassmann of record in the Office Action mailed June 18, 2003, Pages 9-13 Paragraph 13, have been withdrawn due to Applicant's amendments and arguments in the Paper filed November 18, 2003.

6. The 35 U.S.C. 103 rejections of claims 32-34 and 46-48 over Heilmann et al in view of Strassmann and in further view of Takeuchi of record in the Office Action mailed June 18, 2003, Pages 13-15 Paragraph 14, have been withdrawn due to Applicant's amendments and arguments in the Paper filed November 18, 2003.

NEW REJECTIONS

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 18-26, 28-30, 32-51, 53-55, and 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama et al (JP 09-254339) in view of Hotta (USPN 4,588,777).

Kodama et al teach a multilayered laminate suitable for use in a medical appliance which is sterilized in use consisting of two layer or three layer laminated body for forming a tube or medical product (see abstract and p.10 Paragraph 12 of translation). The tube consists of a base material or

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intermediate layer in the three-layer body having 95-20% polypropylene resin and 5-80% hydrogenated diene-based polymer (p.8 Paragraph 11 of translation). The inner and/or outer layer of the body consists of 100-50% polypropylene resin and 0-50% hydrogenated diene-based polymer (p.9, paragraph 11 of translation). The hydrogenated diene-based polymer in either the base layer or the other layer comprises a random copolymer or block copolymer comprising styrene and butadiene, isoprene, or a mixture of isoprene and butadiene (p.7 Paragraph 6 of translation). The styrene content is between 5 and 60% and the vinyl content of the butadiene and/or isoprene is 50% or more. The rate of hydrogenation of the hydrogenated diene system is 90% or more (p.7, Paragraph 6 of translation). The elastic modulus of the entire tube is less than 30MPa (p.11, Table 1 of translation), which is the same as the entire tube of the instant invention, therefore the flexural modulus of the polypropylene resin in the two resin is inherently the same in Kodama et al as the instant invention. Because the Kodama et al body is formed from the same composition, structure, and method the body obviously has peel strength similar to the peel strength of the instant invention. The body is an article used in the medical field (p.16, Paragraph 26 of translation).

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Kodama et al fail to explicitly teach that the multilayer laminate is used to form a medical tube. Kodama et al teach that the laminate is used in the medical field as well as many other various fields such as the food industry. Kodama et al also teach that the laminate can be used for rigid stand alone hollow articles such as food containers (p.16, Paragraph 26 of translation. Hotta teaches that synthetic resin compositions similar to the composition taught by Kodama et al are used to form not only sheets as explicitly taught by Kodama et al, but also blocks, shapes, tubes, nets, and bottles (col.6, 1.3-15). Hotta further teaches that in the field of food packaging and medical appliances, which Kodama et al is involved, synthetic resin compositions for molding are desired having superior transparency and softness (col.1, 1.15-20). Also, the composition must be capable of retaining its shape even at high temperatures above 120°C, which is the sterilization temperature, without the disadvantages of PVC (col.2, 1.10-25). Kodama et al teach that the multilayer laminate of Kodama et al is superior in transparency, flexibility, cold resistance, weld seal strength, heat seal intensity, and can be sterilized without damaging the laminate (p.4, abstract of translation). One of ordinary skill in the art would have recognized that the laminate of Kodama et al solves the problems faced in the

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medical and food packaging art as described by both Hotta and Kodama et al, and that molding compositions similar to the laminate of Kodama et al are used to mold sheets, tubes, containers and other molded articles in the food and medical fields, as taught by Hotta.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to adjust the thickness of the layers and form the multilayer laminate of Kodama et al into a tube, because the similar compositions are known to form tubes, as taught by Hotta, and the composition taught by Kodama et al solves the problems addressed by Hotta with respect to medical tubes and packaging.

Regarding claims 21 and 44, Kodama et al teach that the ratio of thickness of the base material layer and the other layer is suitably chosen according to the property and use of the product (p.10 paragraph 12 of translation). It would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to select the ratio of thickness of the layers within the claimed range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art, absent the

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showing of unexpected result. In re Boesch, 205 USPQ 215 (CCPA 1980).

Regarding claims 37-40 and 59-62, Kodama et al and Hotta taken as a whole fails to explicitly teach that the tube is sterilized, or that the tube is connected to a medical device, or that the tube is a blood tube, infusion tube, catheter, balloon catheter, or part of a circuit for extracorporeal circulation. However, it would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to shape the body used in medical applications of Kodama et al to form bodies that are used in forming the particular articles listed above. Furthermore, the intended use of an article receives little patentable weight because articles are defined by their structure not merely stating a use for the article. One of ordinary skill in the art would have also recognized that medical-application films, bags, and tubes are sterilized, in order to protect the user from diseases transmitted by the articles.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to sterilize the medical-application films, bags and tubes taught by Kodama et al and Hotta combined, in order to

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protect the people using the articles from diseases and injections transmitted by unsterilized medical articles.

ANSWERS TO APPLICANT'S ARGUMENTS

8. Applicant's arguments regarding the 35 U.S.C. 112 rejections of claims 18-62 of record have been considered but are moot since the rejections have been withdrawn.

9. Applicant's arguments regarding the 35 U.S.C. 102 rejections of claims 18-20, 22-36, 41-43, and 45-58 as anticipated by Kodama et al have been considered but are moot since the rejections have been withdrawn.

10. Applicant's arguments regarding the 35 U.S.C. 103 rejections of claims 21, 37-40, 44, and 59-62 over Kodama et al have been considered but are moot since the rejections have been withdrawn.

11. Applicant's arguments regarding the 35 U.S.C. 103 rejections of claims 18-31, 35, 37-45, and 49-62 over Heilmann et al in view of Strassmann have been considered but are moot since the rejections have been withdrawn.

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12. Applicant's arguments regarding the 35 U.S.C. 103 rejections of claims 32-34 and 46-48 over Heilmann et al in view of Strassmann in further view of Takeuchi et al have been considered but are moot since the rejections have been withdrawn.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB

March 24, 2004

CPB

[Signature]
HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

3/29/04